UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/448,378	11/23/99	BRASEL K	2836-D

022932
IMMUNEX CORPORATION
LAW DEPARTMENT
51 UNIVERSITY STREET
SEATTLE WA 98101

HM12/0130

EXAMINER	
VANDER VEGT, F	
ART UNIT	**PAPER NUMBER**
1644	8

DATE MAILED: 01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/448,378	Applicant(s) Brasel et al
	Examiner F. Pierre VanderVegt	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Oct 20, 2000* .

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), ~~or thirty days, whichever is longer,~~ from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *6, 7, 20, and 22-56* ~~is~~/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *6, 7, 20, and 22-56* ~~is~~/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application is a continuation of application 08/725,540.

Claims 1 and 2 have been canceled.

New claims 44-56 have been added.

Claims 6, 7, 20 and 22-56 are currently pending in this application.

1. In view of the amendment filed October 20, 2000, no outstanding rejections are maintained.

2. **The following new ground of rejection was necessitated by Applicant's amendment.**

Claim Rejections - 35 USC § 112

3. Claims 6, 7, 20 and 22-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

The claims are drawn to a method for augmenting an immune response to a cancer in an individual through the administration to the individual Flt-3 ligand and have been amended to recite "and administering an antigen to the patient" in base claims 6 and 20. The purpose of the administration of Flt-3 ligand to the individual being treated in the instant invention is understood to be the stimulation of increased production of dendritic cells, thereby providing the treated individual with increased antigen presentation capacity. The claims are not enabled for treatment of cancer because the claims do not specify, nor does the specification disclose, the nature of the said antigens beyond stating "tumor cell" or "tumor antigen" in dependent claims 44, 45, 49 and 50. The claims are so broad as to encompass ANY molecule which may induce an immune response and no antigens are disclosed in the specification which may be effective in the treatment of cancer. The identification of "antigenic molecules" for use as effective agents as an immunotherapeutic composition in the treatment of cancers would not have been routine to one

of ordinary skill in the art at the time the invention was made. Furthermore, the specification discloses no effective immunotherapeutic approaches to the treatment of cancer using any antigen, only the injection of tumor bearing mice with Flt-3 ligand as set forth in example 3. Further, the methods disclosed in the specification and the claims are specifically drawn to methods for the treatment of cancer utilizing immunotherapeutic compositions which comprise an antigenic molecule and, therefore, the claims read on a cancer vaccine. The state of the art of cancer vaccines is discussed by Falo et al (U). The Falo et al reference teaches that "[a]lthough vaccination has been applied with considerable success to the prevention of infectious diseases, successful tumor vaccination strategies have been particularly elusive. It has long been recognized that tumors can stimulate immune responses in their hosts. Inflammatory infiltrates at the sites of malignancies and lymphocytic proliferation in the draining lymph nodes suggest tumor immunogenicity. Immune effector cells, including T-lymphocytes, natural killer cells, polymorphonuclear neutrophils, macrophages, and dendritic cells, have all been identified in tumor infiltrates. Humoral immune responses to tumors have also been observed, and antibodies specific for antigens expressed on tumor cells have been identified in several tumor models. Such antitumor antibodies, when either elicited by active immunization or administered as passive immunotherapy, can mediate the lysis of tumor targets in murine models and in some human tumors." Falo et al further teach that despite the evidence supporting the existence of an antitumor response in hosts, success has been limited in attempts to elicit an antitumor response in humans and yet there is optimism on the part of tumor immunologists about the future of cancer vaccines based upon advances in the understanding of the role of cytotoxic T cells (CTLs) in antigen-specific immune responses to tumor antigens (page 1041, first column in particular). Falo et al also teach that "T cells, including CTLs, appear to be a critical component of the immune response to tumors. CTL responses are sufficient to protect against tumors and can eliminate even established cancers in murine models and in humans" (page 1041, bridging columns in particular). Falo et al teaches also that there are two major hurdles which must be overcome for

effective cancer vaccine development. The first is that the tumor antigens recognized by CTLs must be identified. The instant specification does not provide, however, any guidance regarding the identification of antigenic molecules which would be effective in stimulating a specific anti-tumor response, nor does it provide guidance for the treatment of one type of cancer with tumor cells of another cancer type, as encompassed by the claims. The second is that even after such a tumor-specific antigen is identified, eliciting a strong CTL response to these targets has been problematic. While working examples are not necessarily a requirement to obtain a patent, given the state of the art at the time the invention was made, the specification does not provide sufficient guidance for one skilled in the art to have used the claimed invention without an undue amount experimentation at the time the invention was made.

In view of the nature of the invention (anti-tumor vaccines), the quantity of experimentation necessary on the part of a skilled artisan at the time the invention was made to use the invention, the limited working examples, the state of the art and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2000 366-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
January 29, 2001

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1800 1640